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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/006,740	12/05/2001	Alexander MacGregor	23936-176	2553

20985 7590 05/31/2005

FISH & RICHARDSON, PC  
12390 EL CAMINO REAL  
SAN DIEGO, CA 92130-2081

EXAMINER

FUBARA, BLESSING M

ART UNIT PAPER NUMBER

1618

DATE MAILED: 05/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<p align="center"><b>Office Action Summary</b></p>	<b>Application No.</b> 10/006,740	<b>Applicant(s)</b> MACGREGOR, ALEXANDER	
	<b>Examiner</b> Blessing M. Fubara	<b>Art Unit</b> 1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 22 February 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-8,10-32 and 34-36 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-8,10-32 and 34-36 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

RD

### **DETAILED ACTION**

Examiner acknowledges receipt of request for continued examination, amendment and remarks filed 02/22/2005. Claims 1, 3-8, 10-32 and 34-36 are pending.

#### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicants' submission filed on 02/22/05 has been entered.

#### ***Claim Rejections - 35 USC § 103***

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. Claims 1, 3-8, 10-32 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fritsch et al. (US 5,213,794).

Fritsch discloses a tablet formulation that comprises polyacrylic acid/methacrylate copolymer, polyvinylpyrrolidone, propylene glycol, calcium polycarbophil, crospovidone, silica, saccharin sodium, banana flavoring and calcium stearate (example 1 and column 6, lines 34-53). The combination of polyvinylpyrrolidone and the acrylate polymer is equivalent to the hydrostatic couple of the instant claims. The active ingredient in Fritsch is antacid (abstract and examples 1 and 2). The swelling capacity recited in claim 3 is a property of the polymer and since the property of a compound or formulation cannot be separated from the compound or

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formulation, the formulation of Fritsch would inherently have the properties recited in claim 3.

The hydrostatic pressure-modulating agent comprises a hydrophilic cross-linked polymer.

Fritsch does not disclose the ratio of the hydrodynamic fluid-imbibing polymer to the hydrostatic pressure modulating as is recited in the instant claim 1. There is no demonstration in the instant specification that the ratio of the hydrodynamic fluid-imbibing polymer to the hydrostatic pressure modulating as is recited in the instant claim 1 confers unusual characteristic results to the delivery system. Differences in amounts or concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such amount or concentration is critical. And “[w]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.” *In re Aller*, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare and use the delivery system of Fritsch. One having ordinary skill in the art would have been motivated to use appropriate amounts of the hydrodynamic fluid-imbibing polymer and hydrostatic pressure modulating with the expectation of delivering the active agent of choice.

3. Claims 1, 3-8, 10-32 and 34-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over (US 5,582,838).

Rork discloses a tablet formulation (column 7, lines 21-42) comprising pharmaceutically active ingredients such as antimicrobials, local anesthetic, analgesics and anti-inflammatory agents (column 6, lines 18, 20, 24 and 18), excipients such as lactose, magnesium stearate, polyvinylpyrrolidone and dyes (column 8, lines 13-25), CARBOPOL polymer (column 8, lines

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45-65) and carbonate (claims 10). See also column 13, line 20 to column 14, line 9). The combination of the CARBOPOL and the polyvinylpyrrolidone constitutes the hydrostatic couple of the instant application. The carbonate is the carbon dioxide precursor of the instant application. Rork teaches particulate formulation (column 8, lines 21-25) and the pharmaceutically active agents are present in amounts of from about 0.01% to about 75% of the core-weight (column 8, lines 26-32). Regarding claims 3 and 5, the formulation of Rork would inherently have the recited property. Regarding claim 15, which depends back to claim 2, it is noted that there is no specific amount of the acrylic polymer recited in claim 2, and thus, the acrylic polymer of the prior art would inherently have the same viscosity if the viscosity measurement is conducted on a 0.5% of the polymer of the prior art. Regarding claim 10, one of ordinary skill in the art has the ability to determine how much carbonate would be required for expansion of the dosage form for the release of actives. Applicant has no comparable example to demonstrate that the particle size recited in claims 19 and 16 provides unusual results. Rork does not disclose the ratio of the hydrodynamic fluid-imbibing polymer to the hydrostatic pressure modulating as is recited in the instant claim 1. It would have been obvious to one of ordinary skill in the art at the time the invention was made to prepare a tablet formulation that comprises nifedipine and the hydrostatic couple of polyvinylpyrrolidone and CARBOPOL according to the teachings of Rork. One having ordinary skill in the art would have been motivated to use appropriate amount of the CARBOPOL with the expectation of achieving the desired delivery.

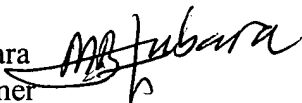
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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara  
Patent Examiner  
Tech. Center 1600

A handwritten signature in black ink, appearing to read "Blessing Fubara", is written over the printed name and title.